K061194

AUG 24 2006

smiths

SECTION 5, 510(k) Summary

Smiths Medical ASD, Inc.
Anesthesia and Safety Devices Division
10 Bowman Drive
Keene, NH 03431-0724 USA
Tel: +1 603 352 3812
Fax: +1 603 352 3703
www.smiths-medical.com

Company Information:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene, NH 03431
(603) 352-3812, prompt 4, ext 2493
Contact: Brian D. Farias
Regulatory Affairs Manager

Summary Prepared: April 27, 2006

Product Name:

Trade Name: **Portex® Needle-Pro® EDGE™ Safety Device with Syringe**

Common Name: Syringe with attached needle and needle protection.

Classification Name: Syringe, Piston (21 CFR 880.5860, Product Code MEG)

Predicate Device(s):

K041399 (Smiths Medical ASD, Inc.) Hypodermic Needle-Pro® EDGE™ Needle Protection Device

K030683 (Nipro Corporation) Nipro® Disposable Syringes

Device Description:

This device consists of the two predicate devices preattached, packaged and sterilized. This device is intended for use to inject fluids into or withdraw fluids from the body. The needle protection device covers the needle after use to help prevent needle sticks. The device features a "one-piece" design of needle hub and protective sheath with a living hinge. The needle cannula is permanently affixed into the hub. The sheath has an "arrow" indicating the bevel orientation, i.e. when the sheath is oriented to the right, the bevel is in the "up position". After the procedure is completed, the needle is pressed into the sheath using a one-handed technique. As the needle enters the protective sheath, the needle is engaged under the hook and contained within the sheath. The device is then discarded into a sharps container.

K061194

Indications for Use:

This device is intended for use to inject fluids into or withdraw fluids from the body. The needle protection device covers the needle after use to help prevent needle sticks.

Technological Characteristics:

The proposed and predicate devices are made of the EXACT same materials and employ the same hinged style protective sheath that is manually activated after use.

Non-Clinical Data:

This abbreviated 510(k) submission declares conformance to the following standards:

ISO 594-1:1986(E), International Standard, *Conical fittings with a 6% taper for syringes, needles and certain other medical equipment-Part 1: General requirements*

ISO 594-2:1998(E), International Standard, *Conical fittings with a 6% taper for syringes, needles and certain other medical equipment-Part 2: Lock Fittings*

ISO 7864:1993(E), International Standard, *Sterile hypodermic needles for single use*

ISO 7886-1:1993, International Standard, *Sterile hypodermic syringes for single use*

Clinical Data:

Not required

Conclusion:

The standards compliance demonstrates that the proposed device is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,

SMITHS MEDICAL ASD, INC.

Brian D. Farias
Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 2006

Mr. Brian D. Farias,
Regulatory Affairs Manager
Smiths Medical ASD, Incorporated
Anesthesia and Safety Devices Division
10 Bowman Drive
Keene, New Hampshire 03431-0724

Re: K061194
Trade/Device Name: Portex Needle-Pro Edge Safety Device with syringe
22 g 1inch needle with 3 ml syringe
23 g 1inch needle with 3 ml syringe
25 g 1inch needle with 3 ml syringe
25 g 5/8 inch needle with 3 ml syringe
Regulation Number: 880.5860
Regulation Name: Syringe, Antistick
Regulatory Class: II
Product Code: MEG
Dated: August 18, 2006
Received: August 21, 2006

Dear Mr. Farias:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

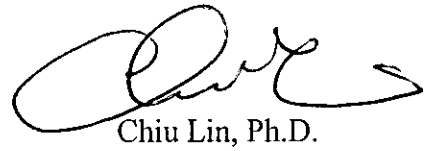
If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): K061194

Device Name: **Portex® Needle-Pro® EDGE™ Safety Device with Syringe**

Indications for Use:

This device is intended for use to inject fluids into or withdraw fluids from the body. The needle protection device covers the needle after use to help prevent needle sticks.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page _1_ of _1__

...sion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices

...(k) Number: K061194